JUL - 5 2006

Section 5
510(k) Summary for the
Lumenis One Family of Systems

K060448

I. General Information

Submitter: Lumenis, Inc.
2400 Condensa Street
Santa Clara, CA 95051

Contact Person: Connie Hoy
Vice President, Global RA/QA

Lisa Scott
Manager, RA/QA

Summary Preparation Date: June 30, 2006

II. Names

Device Names: Lumenis One Family of Systems; Lumenis One

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems (K020839, K024093, K030342, K030527);
- LightSheer Pulsed Diode Array Laser System (K973324, K974346, K982940, K001746, K003614);
- Aluma Skin Renewal System (K051214);

IV. Product Description

Lumenis One systems are comprised of the following main components:

- System console;
- Control and Display;
- One or more delivery handpieces, the Treatment Heads (up to three attached out of four handpieces available for each system);
- Skin cooling technology integrated into the handpiece (as applicable);
- Trigger button integrated into the handpiece; an additional safety button integrated into the laser handpieces;
- Remote interlock connector (disables pulse emission when treatment room door is opened).

V. Indications for Use

The Lumenis One Family of Systems (and the delivery accessories that are used with them to deliver light and/or laser and/or RF energy) is indicated for use in surgical, aesthetic and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology as follows:

➢ Intense Pulsed Light (IPL) Wavelengths (515 - 1200 nm):

The 515–1200 nm intense pulsed light wavelengths are indicated for:

- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
- The treatment of tattoos;
- The treatment of cutaneous lesions, including warts, scars and striae;
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[1], hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

➢ Nd:YAG Laser Wavelength (1064 nm):

The 1064 nm wavelength produced by the Nd:YAG laser is indicated for:

- The coagulation and hemostasis of vascular lesions and soft tissue, including:
  - Treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1 – 4.0 mm diameter) of the leg;
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[1], hair reduction in skin types I-V through selective targeting of melanin in hair follicles;
- The non-ablative treatment of facial wrinkles.

➢ LightSheer Diode Laser Wavelength (800 nm):

The 800 nm wavelength produced by the LightSheer diode laser is indicated for:

- The removal of unwanted hair, and to effect stable long-term, or permanent[1], hair reduction through selective targeting of melanin in hair follicles;
- The treatment of vascular lesions, including angiomas, hemangiomas telangiectasia and other benign vascular lesions;
- The treatment of leg veins;
- The treatment of benign pigmented lesion;
- The treatment of pseudofolliculitis barbae;

The LightSheer diode laser is intended for use on all skin types (Fitzpatrick skin types 1 – VI), including tanned skin.

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[1] Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

➢ **Aluma RF Energy (468 kHz):**

The Aluma 468 kHz energy is indicated for:

- The Aluma Skin Renewal System is intended for use in Dermatologic and General Surgical procedures for the non-invasive treatment of wrinkles and rhytids.

VI. Rationale for Substantial Equivalence

The Lumenis One Family of Systems share the same intended uses as the predicate devices—the Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems (K020839, K024093, K030342, K030527), the LightSheer Pulsed Diode Array Laser System (K973324, K974346, K982940, K001746, K003614), and the Aluma Skin Renewal System (K051214), in that they are intended for use for the same surgical, aesthetic and cosmetic applications in general and plastic surgery, and dermatology.

The Lumenis One Family of Systems share the same indications for use as the predicate devices.

The technical specifications, including the range of treatment parameters, the basic control system, and delivery devices of the Lumenis One Family of Systems are identical or similar to the predicate devices.

VII. Safety and Effectiveness Information

The Lumenis One Family of Systems share the same indications for use and the same or similar technical specifications as the currently marketed predicate Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems (K020839, K024093, K030342, K030527), the LightSheer Pulsed Diode Array Laser System (K973324, K974346, K982940, K001746, K003614), and the Aluma Skin Renewal System (K051214). The small differences that exist in certain technical specifications are not significant and they do not alter the safety or effectiveness of the Lumenis One Family of Systems. Clinical data therefore was not provided.

VIII. Conclusion

Based on the foregoing, the Lumenis One Family of Systems were found to be substantially equivalent to the predicate devices, Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems (K020839, K024093, K030342, K030527), the LightSheer Pulsed Diode Array Laser System (K973324, K974346, K982940, K001746, K003614), and the Aluma Skin Renewal System (K051214), all marketed by Lumenis.

The Lumenis One Family of Systems share the same indications for use and similar or identical design features, functional features, and technical specifications, and thus are substantially equivalent to, the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2006

Lumenis, Inc.
c/o Ms. Martha Murari
2400 Condensa Street
Santa Clara, California 95051

Re: K060448
Trade/Device Name: Lumenis One Family of Systems
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulatory Class: II
Product Code: GEX
Dated: May 16, 2006
Received: May 17, 2006

Dear Ms. Martha Murari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060448

Device Name: **Lumenis One Family of Systems**

Indications for Use:

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- **Intense Pulsed Light (IPL) Wavelengths (515 - 1200 nm):**

The 515–1200 nm intense pulsed light wavelengths are indicated for:

- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
- The treatment of tattoos;
- The treatment of cutaneous lesions, including warts, scars and striae;
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[1], hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

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Prescription Use ☒ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ☐ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

[1] Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

510(k) Number K060448

➢ **Nd:YAG Laser Wavelength (1064 nm):**

The 1064 nm wavelength produced by the Nd:YAG laser is indicated for:

- The coagulation and hemostasis of vascular lesions and soft tissue, including:
  - Treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1 – 4.0 mm diameter) of the leg;
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[1], hair reduction in skin types I-V through selective targeting of melanin in hair follicles;
- The non-ablative treatment of facial wrinkles.

➢ **LightSheer Diode Laser Wavelength (800 nm):**

The 800 nm wavelength produced by the LightSheer diode laser is indicated for:

- The removal of unwanted hair, and to effect stable long-term, or permanent[1], hair reduction through selective targeting of melanin in hair follicles;
- The treatment of vascular lesions, including angiomas, hemangiomas telangiectasia and other benign vascular lesions;
- The treatment of leg veins;
- The treatment of benign pigmented lesion;
- The treatment of pseudofolliculitis barbae;

The LightSheer diode laser is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

➢ **Aluma RF Energy (468 kHz):**

The Aluma 468 kHz energy is indicated for:

- The Aluma Skin Renewal System is intended for use in Dermatologic and General Surgical procedures for the non-invasive treatment of wrinkles and rhytids.

Prescription Use ___☒___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___☐___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K060448